

colorectal cancer screening tests, regardless of whether therapeutic intervention is required during the screening, and for other purposes.”.

A motion to reconsider was laid on the table.

HENRIETTA LACKS ENHANCING CANCER RESEARCH ACT OF 2019

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 1966) to direct the Comptroller General of the United States to complete a study on barriers to participation in federally funded cancer clinical trials by populations that have been traditionally underrepresented in such trials, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 1966

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Henrietta Lacks Enhancing Cancer Research Act of 2019”.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Only a small percent of patients participate in cancer clinical trials, even though most express an interest in clinical research. There are several obstacles that restrict individuals from participating including lack of available local trials, restrictive eligibility criteria, transportation to trial sites, taking time off from work, and potentially increased medical and nonmedical costs. Ultimately, about 1 in 5 cancer clinical trials fail because of lack of patient enrollment.

(2) Groups that are generally underrepresented in clinical trials include racial and ethnic minorities and older, rural, and lower-income individuals.

(3) Henrietta Lacks, an African-American woman, was diagnosed with cervical cancer at the age of 31, and despite receiving painful radium treatments, passed away on October 4, 1951.

(4) Medical researchers took samples of Henrietta Lacks’ tumor during her treatment and the HeLa cell line from her tumor proved remarkably resilient.

(5) HeLa cells were the first immortal line of human cells. Henrietta Lacks’ cells were unique, growing by the millions, commercialized and distributed worldwide to researchers, resulting in advances in medicine.

(6) Henrietta Lacks’ prolific cells continue to grow and contribute to remarkable advances in medicine, including the development of the polio vaccine, as well as drugs for treating the effects of cancer, HIV/AIDS, hemophilia, leukemia, and Parkinson’s disease. These cells have been used in research that has contributed to our understanding of the effects of radiation and zero gravity on human cells. These immortal cells have informed research on chromosomal conditions, cancer, gene mapping, and precision medicine.

(7) Henrietta Lacks and her immortal cells have made a significant contribution to global health, scientific research, quality of life, and patient rights.

(8) For more than 20 years, the advances made possible by Henrietta Lacks’ cells were without her or her family’s consent, and the revenues they generated were not known to or shared with her family.

(9) Henrietta Lacks and her family’s experience is fundamental to modern and future

bioethics policies and informed consent laws that benefit patients nationwide by building patient trust; promoting ethical research that benefits all individuals, including traditionally underrepresented populations; and protecting research participants.

SEC. 3. GAO STUDY ON BARRIERS TO PARTICIPATION IN FEDERALLY FUNDED CANCER CLINICAL TRIALS BY POPULATIONS THAT HAVE BEEN TRADITIONALLY UNDERREPRESENTED IN SUCH TRIALS.

(a) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall—

(1) complete a study that—

(A) reviews what actions Federal agencies have taken to help to address barriers to participation in federally funded cancer clinical trials by populations that have been traditionally underrepresented in such trials, and identifies challenges, if any, in implementing such actions; and

(B) identifies additional actions that can be taken by Federal agencies to address barriers to participation in federally funded cancer clinical trials by populations that have been traditionally underrepresented in such trials; and

(2) submit a report to the Congress on the results of such study, including recommendations on potential changes in practices and policies to improve participation in such trials by such populations.

(b) INCLUSION OF CLINICAL TRIALS.—The study under subsection (a)(1) shall include review of cancer clinical trials that are largely funded by Federal agencies.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Oregon (Mr. WALDEN) each will control 20 minutes.

The Chair recognizes the gentleman from New Jersey.

GENERAL LEAVE

Mr. PALLONE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on H.R. 1966.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New Jersey?

There was no objection.

Mr. PALLONE. Mr. Speaker, I yield the balance of my time to the gentleman from Maryland (Mr. MFUME).

The SPEAKER pro tempore. Without objection, the gentleman from Maryland will control the balance of the time of the majority.

There was no objection.

Mr. MFUME. Mr. Speaker, I thank the chair of the Energy and Commerce Committee, Mr. PALLONE of New Jersey. I appreciate his oversight of this bill and the way his committee has moved us to where we are today.

Mr. PALLONE and I go way back. When I left this body some time ago, I didn’t know I would come back and he would be chair of the committee, but I couldn’t think of a better person.

I also say to Mr. WALDEN, the ranking member from Oregon, that the body obviously will miss you. And as you heard on both sides of the aisle with the comments that have been made, people have respected your leadership and the leadership that you have

brought to that committee both as ranking member and as chair. By the way, let me tell you, there is life after Congress. I went out and found 24 years of it before coming back. So best of everything to you, sir.

Members of the body, if I might, let me just talk a bit about a distinguished, in my opinion, woman whose picture is here beside me. Her name was Henrietta Lacks. She was born 100 years ago in Roanoke, Virginia.

Mrs. Lacks and her husband and her family later moved to Baltimore County in 1941, seeking, as a lot of people did, what they thought were jobs that were available the further north you moved. They moved to an area near what was known as the old Bethlehem Steel Plant. Henrietta and her family lived not far from me and my family in a segregated Black enclave known as Turner Station.

Ironically, Mrs. Lacks got ill. In 1951, as a young mother, she went to the hospital complaining of vaginal bleeding. She went to Johns Hopkins at the time, which was one of the few hospitals that African Americans could go to and be treated.

Upon examination, gynecologists discovered a large, malignant tumor in her cervix. During her treatment there, two cell samples were taken from Mrs. Lacks and from her cervix without her permission and without her knowledge. One sample was healthy tissue, the other sample was cancerous tissue. And these samples were given to a physician and a cancer researcher at Hopkins to study.

What this researcher would soon discover was that Mrs. Lacks’ cells were unlike any others he had ever seen. Where other cells would die, Mrs. Lacks’ cells doubled every 20 to 24 hours.

□ 1500

This continued after her death.

The cells from the cancerous sample became known eventually as the HeLa immortal cell line.

The HeLa immortal cell line is the oldest and the most commonly used human cell line in scientific research anywhere in the world. The cell line was found to be remarkably durable and prolific, which allows its use extensively in scientific study. This was the first human cell line to prove to be successful in in vitro studies, which was a scientific achievement with profound implications on the future and profound benefits to medical research.

HeLa cells can divide an unlimited number of times in a laboratory cell culture plate as long as fundamental cell survival conditions are met and sustained. There are, as we have come to know over time, many strains of HeLa cells as they continue to mutate in other cell cultures, but all HeLa cells are descended from the same tumor cells once removed from Mrs. Lacks. The total number of HeLa cells that have been propagated in cell culture far exceeds the number of cells that were in her body.

Today, these incredible cells are used to study the effects of toxins, drugs, hormones, and viruses on the growth of cancer cells without having to experiment on humans while that is being done. They have been used to test the effects of a number of different things: radiations, poisons, to study the human genome, and to learn more about how all viruses ultimately work, and they have played a crucial role in the development of the polio vaccine.

When Jonas Salk was so close to getting to what he thought was an effective vaccine, Dr. Salk tested the vaccine against the cells, and the cells directed him to make the vaccine even more potent.

The NIH analyzed and evaluated scientific literature over the course of time involving HeLa cells and found that over 110,000 publications cited the use of those cells from 1953 to 2018. So this analysis, I think, further highlights the persistent impact of HeLa cells in science and in medicine, proving that they have been a consistent and essential tool that has allowed researchers to expand their knowledge base in fields such as cancer biology, infectious disease, and many, many other areas.

There is so much to be said about Ms. Lacks, who died in that same Black, poor enclave many, many years ago, but to her credit and to the credit of all science, her living clearly was not in vain, and her death has proven something that nobody ever anticipated at the time: that there could even be such a cell that would continue to develop and mutate long beyond the donor's ability to live.

Mr. Speaker, I reserve the balance of my time.

Mr. WALDEN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I thank the gentleman from Maryland (Mr. MFUME) for bringing us this legislation and for his very kind comments about my service and the future that lies ahead of me, perhaps. I appreciate his leadership and his kind words.

I, too, rise today to speak on H.R. 1966, the Henrietta Lacks Enhancing Cancer Research Act of 2019, which was sponsored by the late, great Representative Elijah Cummings originally.

This bill is named after Henrietta Lacks, a woman of color who donated her cells, without her knowledge and consent, to Johns Hopkins in 1951, beginning what was the first human cell line able to reproduce indefinitely.

Her cells have been used in biomedical research around the world.

H.R. 1966 requires the Government Accountability Office, or the GAO, to study how Federal agencies have addressed barriers to participation in cancer clinical trials by individuals from underrepresented populations and to provide recommendations for addressing such barriers.

The intent of the bill is laudable, as racial and ethnic minorities are currently underrepresented in clinical trials.

I know that has been an issue even in the COVID trials. I have talked to the people who have developed these vaccines, and this is a real issue they face, trying to get the right mix to reflect the community and make sure that everyone who takes the various drugs and vaccines are represented in these trials.

It is a concern, because people of different ages, different races, different ethnicities, they simply may react differently to medical treatments. So we have to get this right.

Mr. Speaker, I appreciate my friends from Maryland for bringing this legislation to the floor, and I, of course, pay homage to Representative Cummings for his initial leadership on this as well.

Mr. Speaker, I reserve the balance of my time.

Mr. MFUME. Mr. Speaker, I yield 5 minutes to the gentleman from Maryland (Mr. RUPPERSBERGER) of the Committee on Appropriations.

Mr. RUPPERSBERGER. Mr. Speaker, I rise in support of H.R. 1966, and I thank the gentleman for yielding.

I proudly co-led this bill when it was first introduced by our late friend, Elijah Cummings, in honor of the extraordinary life and legacy of a Baltimore native, Henrietta Lacks.

Although Congressman Cummings has passed on and remains deeply missed, I am proud and grateful that Congressman MFUME has picked up the mantle on this important legislation.

Without her knowledge or permission, doctors used Henrietta Lacks' cells for medical research that eventually led to some of medicine's most critical breakthroughs, including development of the polio vaccine, along with treatments for cancer, HIV/AIDS, leukemia, and Parkinson's.

I can think of only a handful of Marylanders or even Americans who have contributed more to modern medicine than Henrietta Lacks. Her life-saving contributions will continue to advance cures for debilitating diseases for generations to come.

Yet more than 70 years after Henrietta Lacks' death, many communities still face glaring health disparities. For example, while cancer incidence rates are highest among non-Hispanic White females, non-Hispanic Black females have the highest rate of death.

Clinical trials are a key component to advancing cancer research and treatment, but 20 percent of cancer clinical trials fail because of a lack of patient enrollment, with racial and ethnic minorities and older, rural, and lower-income Americans generally underrepresented in such trials.

This bill examines access to government-funded cancer clinical trials for traditionally underrepresented groups, but it is also about much more.

It is about giving credit where credit has been long overdue, it is about ensuring all Americans get the medical treatments they deserve, and it is

about ensuring clinical trials succeed because they are inclusive.

Mr. Speaker, I urge all of my colleagues to support this bill.

Mr. WALDEN. Mr. Speaker, I yield such time as he may consume to the gentleman from Oklahoma (Mr. KEVIN HERN).

Mr. KEVIN HERN of Oklahoma. Mr. Speaker, I thank the gentleman from Oregon (Mr. WALDEN) for yielding.

I rise in support of H.R. 1966.

This legislation was first brought to my attention by my constituent, Carla Prothro, who is fighting cancer. We talked about the way clinical trials impact the treatments available for cancer patients. The trials very rarely reflect the population of cancer patients.

When women and minorities are underrepresented in clinical trials, it negatively impacts the results. About one in five cancer trials fail because of a lack of participation.

This bill addresses that by studying the barriers to participation for underrepresented groups. We need to find ways to reduce those barriers and enroll more patients from diverse backgrounds.

My niece, Juniper, is 3 years old and fighting stage 4 neuroblastoma. She is just a little kid, but her short life has already had so much pain. She has spent a third of her life in the hospital.

Juniper is a fighter, though, and she has so many people who love her and are praying for her.

Bills like this help Juniper and Carla and millions of cancer patients around the world. Every step forward in cancer research is important. Every bit of progress gets us closer to a better world.

Mr. Speaker, I urge my colleagues to vote in support of H.R. 1966 today.

Mr. MFUME. Mr. Speaker, I reserve the balance of my time.

Mr. WALDEN. Mr. Speaker, I don't have any other speakers on my side. I encourage Members to support this really important legislation, and I yield back the balance of my time.

Mr. MFUME. Mr. Speaker, I would inquire how much time remains on my side.

The SPEAKER pro tempore. The gentleman from Maryland (Mr. MFUME) has 10½ minutes.

Mr. MFUME. Mr. Speaker, I yield myself such time as I may consume.

My thanks, again, to the gentleman from Oregon (Mr. WALDEN) and the others who have spoken on behalf of this, including Congressman RUPPERSBERGER, who has been, as he indicated, a part of this effort for a while.

And that while goes all the way back to the other reason that I am here today, and that is my friend of 42 years and a Member of this body for 23 years, the late Elijah Cummings, who originally introduced this bill before his death, and a commitment that I made to he and to others long ago that, working outside of the Congress, I would be supportive of him.

But now that I am inside, I wanted to make sure that I got unanimous consent from this body, as I did a month

or so back, to be able to assume the leadership of this bill, its sponsorship, and to move it forward, and we have been doing all that we could to get to this point.

Again, Mr. Speaker, I would be remiss if I did not thank Mr. PALLONE and Mr. WALDEN for their efforts.

Let me, if I might, just say a couple of things, Mr. Speaker. It has been long recognized that the burden of cancer is not equal and not equivalent among different racial and ethnic groups in our society. In fact, there is a fourfold increase, or disparity, in the number of Black people diagnosed with cancer in this country as compared with the proportion of Black people participating in clinical trials.

The gentleman from Oregon (Mr. WALDEN) mentioned how sensitive this is right now as we are trying to work with drug companies to come up with a number of vaccines. And whether it was the Pfizer trial or the Moderna trial, one thing is clear: there has never seemed to be enough persons of ethnic backgrounds, particularly African Americans and Latinos, who are participating in these trials.

To underscore this more, let me remind you that 20 percent of Alzheimer's patients in this country are African American, but only 3 to 10 percent are the trial participants in clinical trials.

As I said, COVID is a disease with a roughly twofold higher rate of diagnosis and mortality between African Americans and other populations.

So all of that, in the aggregate, really stresses the need for a more diverse research participatory effort in order to fully understand, comprehensively deal with, and cure these diseases.

Clinical trials are an essential step in advancing potential new cancer treatments. We know that. Patient participation in those trials is absolutely crucial to their success.

Now, many patients will express a willingness to participate in clinical research, yet only a small fraction of those persons do actually do that.

In terms of the larger African-American community, some of the barriers that have existed continue to exist. People can't take time off from their job to participate and be studied in a clinical trial, or, more importantly, there is this level of distrust.

The distrust, particularly among African Americans, goes back to 1932, when our government, through the United States Public Health Service, oversaw and gave authorization for what was to become known as the infamous Tuskegee Study, where 600 Black men, without their knowledge, without their approval or consent, were injected with syphilis and told that they were being treated for something altogether different.

Those 600 men lived and watched their bodies change. Many of them may have had reinfectious others. They suffered a great deal of pain. And nowhere during that time did the government step in and say, "Stop it."

□ 1515

That Tuskegee study, which many of us grew up hearing about, is something that lurks in the minds of a lot of African Americans about why you can't trust the government on research when it comes to your body. The shame that went with that ought to be a collective shame that all of us in this country feel.

We are beyond 1932. People are still getting ill. There are all sorts of infectious diseases. We need vaccines, and we have to find a way now to participate in that process and to find a way to get beyond the things that hold us back.

But in this instance, I just thought it was important to mention why that reluctance tends to exist.

Racial and ethnic groups, and older Americans, rural Americans, and poor Americans, are all the groups that still remain underrepresented in cancer clinical trials. Without action, these groups will continue to face barriers in terms of enrollment in cancer and other clinical trials, which then deprive many Americans from access to effective treatments and effective interventions.

Mr. Speaker, I close by reminding us how we began, and that is with the story, the life, and the lesson of Henrietta Lacks, who died at an early age, a mother of five who came north seeking employment, who developed an illness, who got treated, and who, without her knowledge or consent, had cells taken out of her body that were not cancerous—in addition to the cancerous cells—only to miraculously find that there was something very, very special about Ms. Lacks and her biological makeup: a cell that continued to mutate and to mutate and to double long after it was taken from her body, long after her death, and even now has created 110,000 studies about this miraculous cell, which we call HeLa, that has been the basis of research, Nobel award-winning research, in the years that followed.

My thanks to all of you for participating and for understanding the passion that drove Elijah on this, that drives me on this.

I want to thank the Lacks family, the Henrietta Lacks Foundation.

I want to thank the American Cancer Society, the National Institute of Minority Health and Health Disparities, Research America, and all the other organizations that continue to fight to bring about some sort of balance and equity in the whole issue of research and clinical trials.

Mr. Speaker, I yield back the balance of my time.

Ms. ESHOO. Mr. Speaker, I rise in support of H.R. 1966, the Henrietta Lacks Enhancing Cancer Research Act. I urge my colleagues to support this bill in honor of two Baltimoreans who changed the world—Henrietta Lacks and Representative Elijah Cummings.

Representative Cummings introduced this legislation to help address the barriers facing minority, low-income, and underrepresented

groups when it comes to enrolling in federally-funded clinical cancer trials. He named it after Henrietta Lacks to honor the role she and her tumor samples played in breakthroughs for cancer, HIV/AIDS, leukemia, polio, and Parkinson's disease. Henrietta Lacks' tumor samples were used without her or her family's knowledge or consent and her contribution has been overlooked for decades. This legislation will begin to correct that wrong, while also improving access to medical research for African Americans and other underrepresented groups.

Representative Cummings dedicated his Congressional career to ensuring underrepresented groups had access to health care. He championed policies to improve health equity by lowering drug prices and improving maternal care for African American women. I'm pleased that this bill will be added to his legacy and I thank Representative MFUME for ensuring the advancement of this bill.

I urge my colleagues to support this legislation.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 1966, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

REQUIRING SECRETARY OF HEALTH AND HUMAN SERVICES TO CONSIDER CERTAIN RECOGNIZED SECURITY PRACTICES

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 7898) to amend title XXX of the Public Health Services Act to provide for a technical correction to provide the Inspector General of the Department of Health and Human Service certain authorities with respect to investigations of information blocking, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 7898

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. RECOGNITION OF SECURITY PRACTICES.

Part 1 of subtitle D of the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. 17931 et seq.) is amended by adding at the end the following:

“SEC. 13412. RECOGNITION OF SECURITY PRACTICES.

“(a) IN GENERAL.—Consistent with the authority of the Secretary under sections 1176 and 1177 of the Social Security Act, when making determinations relating to fines under such section 1176 (as amended by section 13410) or such section 1177, decreasing the length and extent of an audit under section 13411, or remedies otherwise agreed to by the Secretary, the Secretary shall consider whether the covered entity or business associate has adequately demonstrated that it had, for not less than the previous 12 months, recognized security practices in place that may—